

# Influenza Vaccine Bulletin #2

September 8, 2005

Influenza Season 2005-06

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) publishes and distributes periodic bulletins to update partners about recent developments related to the production, distribution, and administration of influenza vaccine. All recipients of this bulletin are encouraged to distribute each issue widely to colleagues, members, and constituents.

## Influenza Vaccine Supply and Production

### Projection for the 2005-06 Influenza Vaccine Supply

Sanofi pasteur representatives have announced publicly that they plan to produce between 50 and 60 million doses and MedImmune representatives indicate that about 3 million doses of their Live Attenuated Influenza Vaccine (LAIV) will be available. Meanwhile, Chiron's Liverpool facility is making changes in response to observations and inspections by both the British regulatory authority (MHRA) and the U.S. Food and Drug Administration (FDA). If Chiron is able to complete its remediation plan and secure FDA approval, company officials indicate they plan to produce 18-26 million doses for use in the U.S. On August 31, 2005, FDA informed Chiron that their "responses and proposed corrective actions" following the FDA inspection in July were "generally acceptable." A company press release notes that they must still obtain supplemental FDA approvals. In late May, 2005, GlaxoSmithKline (GSK) submitted a Biologics License Application to the FDA for its influenza vaccine, and the FDA licensed that vaccine on August 31. Company officials have indicated that they plan to sell about 8 million doses in the U.S.

### Influenza Vaccine Presentations

Available presentations for the upcoming season's influenza vaccine vary by manufacturer. MedImmune's FluMist® is available in a single-dose nasal sprayer and contains no thimerosal. The package insert is available at [www.fda.gov/cber/label/inflmed080505LB.pdf](http://www.fda.gov/cber/label/inflmed080505LB.pdf)

Sanofi pasteur offers four different options in its influenza vaccine, Fluzone®: three thimerosal-free single-dose presentations including a 0.25 ml syringe for children 6-35 months of age, and either a 0.5 ml syringe or a 0.5 ml vial for persons ages 3 years and above; and a multi-dose vial with thimerosal as a preservative, licensed for those ages 6 months and above. Note that the package insert and packaging for Fluzone® will continue to use the company's former name, Aventis Pasteur. ([www.fda.gov/cber/products/inflave071405.htm](http://www.fda.gov/cber/products/inflave071405.htm))

Meanwhile, pending FDA and MHRA approvals, Chiron has indicated that they will distribute most of their U.S. product in multi-dose vials with thimerosal as a preservative. They may also provide some 0.5 ml syringes that have trace amounts of thimerosal. This vaccine is licensed for individuals  $\geq 4$  years old.

Finally, GSK will distribute all its U.S. doses in 0.5 ml syringes containing a trace amount of thimerosal remaining from the production process. The GSK product

is licensed for persons ages 18 years and above, and the package insert for this product is available at [www.fda.gov/cber/products/inflgla083105.htm](http://www.fda.gov/cber/products/inflgla083105.htm)

## **Influenza Vaccine Distribution and Administration**

### **Ordering Influenza Vaccine**

- MedImmune still has quantities of its live attenuated vaccine (FluMist™) available for pre-booking.
- Sanofi pasteur continues to pre-book orders for its pediatric influenza vaccine in the pre-filled syringe presentation.
- Distributors for the influenza vaccines produced by Chiron and GlaxoSmithKline have been taking orders for those products. Prospective customers should check with these distributors regarding availability.
- Providers may need to explore several potential sources to find influenza vaccine.

### **Cost for Influenza Vaccine**

Prices for influenza vaccine this year have increased over last year. Purchasers should check with their regular sources of vaccine to determine exact cost.

### **Reports of Inflated Influenza Vaccine Prices or Quotes**

The Centers for Disease Control and Prevention once again is encouraging all health care providers and the general public to report incidents of inflated influenza vaccine prices or quotes. More than 100 reports were received last season, all of which were provided to the state Attorneys General in both the report and vendor states for investigation. Within two weeks of the vaccine shortage announcement, CDC noted a substantial reduction in the number of reports received. For the 2005-2006 influenza season, CDC will initiate a more organized and streamlined protocol for reporting, investigating, and documenting such occurrences. This protocol and a new report form will soon be distributed widely to the health care community.

### **Health Care Provider Vaccination**

The Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) have agreed to publish a joint statement strongly recommending influenza vaccination of health care workers. These recommendations should be issued in the next few months.

### **ACIP Recommendations for Preventing Influenza, 2005-06**

The ACIP's 2005-06 recommendations for preventing influenza were published in the Morbidity and Mortality Weekly Report (MMWR) on July 29, 2005. The entire document can be seen by clicking on the following link:  
[www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm).

A statement titled “Tiered Use of Inactivated Influenza Vaccine in the Event of a Vaccine Shortage” was published in the MMWR on August 6, 2005. The article was intended to encourage contingency planning in the event a tiered approach to influenza vaccination would be necessary during the upcoming influenza vaccination season. To view it, click on

[www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a4.htm).

Since publication of the August 6 MMWR article, CDC has determined that uncertainties remain about the quantity and timing of this year’s influenza vaccine supply. Thus, prudence dictates that a tiered approach to influenza vaccination as described in the August 6 article be implemented through Sunday, October 23, 2005. Specifics are described in an MMWR article published September 2, 2005 and available at:

[www.cdc.gov/mmwr/preview/mmwrhtml/mm5434a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5434a4.htm)

A patient self-screening form for use through October 23 will soon be available on the CDC influenza web site at [www.cdc.gov/flu](http://www.cdc.gov/flu).

### **FDA Allows Influenza Vaccine Redistribution During the 2005-06 Season**

Again this year, the FDA has agreed to allow providers to redistribute influenza vaccine between/among themselves to remedy any maldistribution that may occur as a result of delays in vaccine distribution or shortages. The FDA statement can be found at:

[www.cdc.gov/flu/professionals/vaccination/reallocation0506season.htm](http://www.cdc.gov/flu/professionals/vaccination/reallocation0506season.htm)

## **Influenza Vaccine Communications and Resources**

### **CDC Influenza Vaccine Communications Update**

For the 2005-06 influenza season, CDC will have information and updates for the public, providers, and the press available on its website ([www.cdc.gov/flu](http://www.cdc.gov/flu)), as well as its annual educational print materials for the public and providers. Electronic files of campaign materials are now available for download from the CDC Flu Gallery website ([www.cdc.gov/flu/gallery](http://www.cdc.gov/flu/gallery)). CDC will continue to make appropriate materials available over time.

### **Resource Materials**

#### **Medicare Information**

For a variety of helpful information about Medicare topics such as billing, roster billing, and payment rates, check the following links:

- (1) [www.cms.hhs.gov/preventiveservices/2.asp](http://www.cms.hhs.gov/preventiveservices/2.asp),
- (2) [www.cms.hhs.gov/medlearn/refimmu.asp#edu](http://www.cms.hhs.gov/medlearn/refimmu.asp#edu), and
- (3) [www.cms.hhs.gov/preventiveservices/2.asp](http://www.cms.hhs.gov/preventiveservices/2.asp).

## Morbidity and Mortality Weekly Reports

Review other recently published MMWR articles related to influenza and influenza vaccine by clicking on [www.cdc.gov/flu](http://www.cdc.gov/flu) (under News & Highlights) or by selecting one of the following links.

- For information on 2005-influenza vaccine pre-booking and distribution strategies, go to [www.cdc.gov/mmwr/preview/mmwrhtml/mm5412a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5412a4.htm).
- A complete report on strategies for increasing adult vaccination coverage rates is available at [www.cdc.gov/mmwr/preview/mmwrhtml/rr5405a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5405a1.htm).
- A summary of 2004-05 influenza activity in the U.S. and world-wide is available at [www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a3.htm).
- Efforts to implement surveillance for laboratory-confirmed influenza-associated hospitalizations in Colorado during the 2004-05 season are detailed at [www.cdc.gov/mmwr/preview/mmwrhtml/mm5421a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5421a3.htm).

## Influenza Vaccine Bulletins

Refer to previous bulletins at [www.cdc.gov/flu/professionals/flubulletin.htm](http://www.cdc.gov/flu/professionals/flubulletin.htm). Individual requests for subscriptions to the bulletin should be e-mailed to [listserv@listserv.cdc.gov](mailto:listserv@listserv.cdc.gov) Type *subscribe flu-serve* in the body of the e-mail.

## Upcoming Events

EVENT	LOCATION	2005 DATE(S)
Centers for Medicare & Medicaid Services (CMS) And Centers for Disease Control (CDC) <b>Nursing Home Immunization Satellite Broadcast and Webcast</b> (To register and view instructions visit <a href="http://cms.internetstreaming.com">http://cms.internetstreaming.com</a> . The agenda and handouts for this broadcast will be available on the website no later than September 1, 2005.)	National	September 8, 1-3p.m.
NFID National Influenza Vaccine Summit Press Conference on Influenza and Pneumococcal Vaccination	Washington, DC	September 14
National Adult Immunization Awareness Week (NAIAW)	National	September 25- October 3
National Vaccine Advisory Committee (NVAC) <a href="http://www.hhs.gov/nvpo/nvac/index.html">www.hhs.gov/nvpo/nvac/index.html</a>	Washington, DC	September 27-28
Advisory Committee on Immunization Practices (ACIP) <a href="http://www.cdc.gov/nip/acip">www.cdc.gov/nip/acip</a>	Atlanta, GA	October 26-27